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Subject: OCSPP News for October 22, 2020

OCSPP News Round-Up

TSCA

- Chemical Watch 10/22; EPA chemicals chief wants TSCA fees focused on manufacturers
- Inside TSCA 10/21; OIG to investigate EPA's Endocrine Disruptor Screening Program
- Inside TSCA 10/21; Industry Doubts EPA Will Fulfill Ambitious TSCA Regulatory Agenda In 2020
- Inside TSCA 10/21; EPA Weighs TSCA Uses For Controversial 'Toxicity Threshold' Concept
- WWay News 10/21; Environmental watchdog group alleges EPA allows company to violate environmental law
- Mondaq 10/22; EPA Draft Risk Assessment On Asbestos Flawed And Could Be Problematic For Automotive Friction Defendants

Pesticides

- Bloomberg Law 10/21; Monsanto Review Bid Rejected in California Roundup Case
- Bloomberg Law 10/21; Occidental Chemical Defeats Central Americans' Pesticide Suit
- Successful Farming 10/20; BAYER LAUNCHES ROUNDUP POWERMAX 3 HERBICIDE
- Cision PRWeb 10/22; WSSA Announces Opposition to Weakening of FIFRA Regulations

Blog/OpEd/Other

- B&C Pesticide Law and Policy Blog 10/21; EPA's Draft Residual Efficacy Protocols for "Long-Lasting" Efficacy for Antiviral Products
- The National Law Review (Bergeson & Campbell) 10/21; EPA Reminds Companies of November 1 Deadline to Submit CBI Substantiations for NOA Form A

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EPA chemicals chief wants TSCA fees focused on manufacturers
Jon Kelvy, Chemical Watch
https://chemicalwatch.com/169701/epa-chemicals-chief-wants-tsca-fees-focused-on-manufacturers

As the US EPA prepares to release its proposal to update the TSCA fees rule, the agency is looking at ways to keep charges for administering risk evaluations focused on chemical manufacturers, the head of the agency's chemicals office has said.

The agency is "looking at the types of entities that would be subject to fees to make sure that TSCA fees are really focused on the manufacturers of chemicals", Alexandra Dunn EPA assistant administrator for the Office of Chemical

Safety and Pollution Prevention (OCSPP) said on 16 October, during the final day of Chemical Watch's three-day conference on key regulatory updates for Europe, Asia and the Americas.

The EPA submitted its proposal to amend the 2018 TSCA fees rule to the Office of Management and Budget (OMB) on 14 October for interagency review. Once the OMB completes its review, the proposal will be published in the Federal Register, which will kick off a public comment period.

The proposed amendment is expected to recommend making permanent some of the accommodations the agency made, after an outcry followed its preliminary lists of companies responsible for paying a share of the $1.35m fee that comes with each of the next 20 TSCA risk evaluations for high-priority chemicals.

The agency in March offered a "no action assurance", saying it would exercise its enforcement discretion for three categories of manufacturers:

- those that import a high-priority substance in an article;
- those that produce one as a byproduct; and
- those that produce or import one as an impurity.

Following this, the EPA in September released a final list of companies responsible for the TSCA fees that included about one-quarter that it had originally identified, though retailers like Target Corporation and automakers such as Chrysler Group, Toyota Motors North America and Porsche Cars North America were still present.

Additional exemptions?
Meanwhile, the speciality chemicals industry has called on the EPA to make changes to the TSCA fees rule to reduce the charges for submitting pre-manufacture notices (PMNs). In a letter sent to the EPA in August, the Society of Chemical Manufacturers and Affiliates (Socma) also called for a de minimis exemption from TSCA section 6 risk evaluation fees.

During the conference on 16 October, Ms Dunn was asked about the possibility of including a de minimis exemption for TSCA fee payers. She said stakeholders interested in the idea could bring it up during the public comment period on the proposed rule.

Fees due in January
Companies included on the September-released final list of fee payers have until early January to submit their share of the payment to the EPA. The TSCA fees rule sets out a formula for dividing up the costs, with an 80% discount for small manufacturers.

The EPA has said it is open to considering payment options for companies struggling to meet their fee obligations, but Ms Dunn said the agency's flexibility is limited.

While the agency may be able to provide some "accommodation" for fee payers on a case-by-case basis, "I don't think you'll see us adopting a widespread delayed payment approach," she said. "It's not in our toolbox right now."

Companies on the list also have the option to join or form a fee payer consortia, which can choose to divide the bill among group members. They must notify the EPA that a consortium has been formed by 3 November.

OIG to investigate EPA's Endocrine Disruptor Screening Program
Inside TSCA
https://insideepa.com/tsca-takes/oig-investigate-epa-s-endocrine-disruptor-screening-program

EPA's Office of the Inspector General (OIG) has announced that it will evaluate "EPA's efforts to test all active pesticides for human endocrine disruption activity," a controversial chemical testing program that the Trump EPA has repeatedly sought to eliminate in budget proposals.

OIG explains in an Oct. 21 memo to EPA's toxics chief Alex Dunn that its objectives for the evaluation are to assess the Office of Chemical Safety and Pollution Prevention's (OCSPP) "progress in implementing Section 408(p)(3)(A) of the Food Quality Protection Act, which requires the EPA to test all active pesticides for human endocrine disruption activity," and "compliance with Section 408(p)(6) of the Food Quality Protection Act, which requires EPA to take action -- for example, conduct an endocrine disruption risk assessment -- if testing for a pesticide shows that it disrupts the human endocrine system."

The memo asks Dunn to prepare for an upcoming "entrance conference" a series of materials, including an "explanation of the EPA's plan for and progress in testing all active pesticide ingredients for endocrine disruption" as well as the "number of pesticide active ingredients with current EPA registrations" and lists of pesticide active ingredients "that have completed Tier I endocrine disruptor screening"; "are pending Endocrine Disruptor Screening Program orders and data call-in notices for Tier I endocrine disruptor screening"; "have completed Tier II endocrine disruptor screening"; and "are pending [EDSP] orders and data call-in notices for Tier II endocrine disruptor screening."

The investigation is the latest of a series of OIG inquiries into EPA's toxics programs, many of which are driving changes in how the agency implements its programs. For example, EPA earlier this month agreed with OIG advice to set programmatic goals and collect certain data from industry participants in its Safer Choice cleaning chemical labeling program.

The agency has also agreed to bolster the financial system for its Toxic Substances Control Act (TSCA) program and assess its TSCA workforce needs in response to separate OIG investigations.

EPA developed the EDSP to implement language in the 1996 Food Quality Protection Act directing the agency to assess the endocrine potential of chemicals found in drinking water sources and pesticide ingredient chemicals.

The program has long been controversial, with some toxicologists questioning the need for a program testing chemicals for adverse endocrine effects, while industry has been reluctant to pay for the expensive battery of tests.

Efforts to launch the program, including developing the two-tiered battery of assays with traditional animal toxicology and non-animal methods and issuing testing orders, have also been fraught with technical challenges and bureaucratic hurdles.

In recent years, the Trump administration has repeatedly proposed to eliminate funding for EDSP, though these attempts were repeatedly rejected by Congress. For example, the fiscal year 2020 request proposed eliminating EDSP by zeroing out its FY19 appropriated $7.6 million budget and its 7.7 full-time equivalent (FTE) employees.

While the Congressional Justification document attached to that proposal notes that EDSP was created in response to Congressional direction in the 1996 amendments to the Federal Food Drug and Cosmetic Act and the Safe Drinking Water Act, the justification says that "[r]esources and FTE are proposed for elimination for this program in FY2020. EPA will absorb the remaining functions within the Pesticides Program using the currently available tiered testing battery."

Last month, the agency relocated EDSP during a reorganization of OCSPP, undertaken to bolster its separate toxics and pesticide offices (OPP) to address the growing needs each respectively faces to implement Congress' 2016 reform of TSCA and approve a host of new disinfectants to curb the spread of the coronavirus.

An agency spokesman told Inside TSCA last month that moving EDSP from OCSPP's science policy office to OPP is intended to "align with OPP's statutory obligations under the Federal Food, Drug, and Cosmetic Act, the reorganization moves [the] endocrine disruptor [screening] program [EDSP] to OPP."

Industry Doubts EPA Will Fulfill Ambitious TSCA Regulatory Agenda In 2020
Rick Weber, Inside TSCA
https://insideepa.com/tsca-news/industry-doubts-epa-will-fulfill-ambitious-tsca-regulatory-agenda-2020

EPA has yet to send to the White House draft versions of several key rules for overhauling its TSCA program for both new and existing chemicals that it plans to propose or issue as final this year, prompting some industry lawyers to question whether the agency will meet its ambitious regulatory targets.

"I doubt it. I don't think there's enough time" for EPA to issue its proposed "procedural regulations" for reviewing new chemicals under Toxic Substances Control Act (TSCA) section 5, said James Votaw, partner at the law firm Kellerman and Heckman, in an interview with Inside TSCA.

"EPA is proposing this rule based on the Unified Agenda to help solve the problems that they think they have. That's why I understand why they want to do this," he said.

EPA listed the proposed rule in question in the spring Unified Agenda of federal regulatory activity, pledging to issue a "notice of proposed rulemaking" (NPRM) in September, a deadline that has passed.

The proposal is intended to set "procedures" for companies to submit premanufacture notifications (PMNs) for new chemicals under TSCA section 5.

EPA is required to issue a determination on a PMN within 90 days, a deadline the agency has been struggling to meet. The proposal "seeks to increase the quality of information initially submitted in new chemicals notices and improve the Agency's processes to reduce unnecessary rework in the risk assessment and, ultimately, the length of time that new chemicals are under review," according to the Unified Agenda notice.

Chemical industry groups, which have long sought guidance on the type of data to submit to ensure applications are quickly approved, have welcomed the agency's plan.

"We encourage the agency to continue its efforts to improve transparency, enhance communication with submitters and, most importantly, to meet the statutory requirement for a 90-day review of a new chemical submission," American Chemistry Council spokesman Jon Corley told Inside TSCA.

But environmentalists, who fear EPA is not adequately assessing the chemicals' risks, have raised concerns about the plan, suggesting they may seek to block it should former vice president Joe Biden win the presidential election in November.

"Given how the Trump EPA has misinterpreted the [2016] amendments [to TSCA], I would be worried that new regulations would be solely for the purpose of accelerating [new chemical] reviews and minimizing health and environmental concerns and would expect they would be highly problematic if not unlawful," said Robert Sussman, a former EPA deputy administrator in the Clinton administration who now represents Safer Chemicals, Healthy Families.

EPA's regulatory agenda had also slated a final "framework" rule for developing significant new use rules (SNURs) under TSCA section 5 for August, but the rule still has not been sent to the White House Office of Management and Budget (OMB) for final signoff.

EPA's press office declined to comment on the status of the final rule. But the rule's long-overdue release is adding to industry doubts about the agency's ability to clear its TSCA regulatory agenda this year.

Existing Chemicals

The anticipated NPRM on new chemicals is one of three proposed TSCA rules slated for release this year with only one -- proposed revisions to EPA's TSCA fees rule -- having been sent to OMB for interagency review and final approval.

In addition to the fees proposal, EPA's Unified Agenda also indicated for the first time that the agency would issue a proposed rule under section 8 to help it gather data on chemicals listed in the Obama-era "workplan" from which the agency must select high priority chemicals for review -- and possible regulation -- under TSCA section 6.

"EPA is developing this TSCA section 8(a) rule to obtain information about potential hazards and exposure pathways related to certain chemicals on the TSCA Work Plan, particularly occupational, environmental, and consumer exposure information," according to the Unified Agenda notice. "This information is needed to inform prioritization and risk evaluation of the chemical substances, as mandated under TSCA section 6."

EPA plans to issue an NPRM for the section 8(e) reporting and recording in November, according to the Unified Agenda. But no proposal has been sent yet to OMB.

Generally, there is agreement that EPA will be able to issue final rules this year governing five persistent, bioaccumulative and toxic (PBT) chemicals, which have all been sent separately to OMB for review, as well proposed revisions to the TSCA fees rule submitted to OMB on Oct. 14.

Also, EPA is expected to issue a final rule this year on its controversial science "transparency" requirements, which was sent to OMB on Sept. 14. The rule was developed by EPA's Office of Research and Development, but it will have implications for TSCA and all other environmental programs by requiring that science data used in policy decisions be publicly available and independently verified.

And there is general agreement among sources that EPA will complete the remainder of its first 10 chemical risk evaluations under TSCA section 6 by the end of the year.

Beyond that, other TSCA rulemaking actions slated for this year will likely have to wait, sources say.

Votaw stresses that EPA's desire to propose a rule on PMN procedures is more a priority for the agency than for industry. "They want to move this quickly, and they want to meet their 90 day" deadline for reviewing PMN submissions under TSCA section 5, Votaw said.

"But I think there are other issues that industry has about the way that PMNs are processed," he said. "And I would hope that before the agency would be proposing something that they would do greater outreach to hear more about that. I think that would be extremely useful."

"I would hope that they would take opportunities to collect information from industry not only about the approaches they're thinking about to solve their problems, but to address some of the larger problems with PMNs, particularly since we have so much experience," he said.

But he added that's not likely to happen, at least this year.

"I'm not aware of any public process to collect information ahead of the proposal," Votaw said. -- Rick Weber (rweber@iwpews.com)

EPA Weighs TSCA Uses For Controversial 'Toxicity Threshold' Concept
Maria Hegstad, Inside TSCA
https://insideepa.com/tsca-news/epa-weighs-tsca-uses-controversial-toxicity-threshold-concept

EPA researchers and external stakeholders will soon begin a collaboration to consider ways that a controversial approach to evaluating chemicals with limited toxicity data could be used in TSCA applications for both new and existing chemicals, an agency researcher told EPA's conference on non-animal toxicity testing methods.

The approach, known as threshold of toxicological concern (TTC), establishes a low level of exposure thought to be safe for any chemical, even one with unknown toxicity, based on knowledge of its chemical structure.

To date, it has largely been used in food contact applications by regulatory agencies such as the Food and Drug Administration and the European Food Safety Authority (EFSA), though EPA has previously signaled it plans to use the approach to prioritize existing chemicals for future evaluation under the Toxic Substances Control Act (TSCA).

Its use is backed by industry and animal welfare groups, in part because it allows regulators to avoid or reduce the use of animal studies, but environmentalists are concerned about its use, charging it is unreliable and not protective.

"The collaboration was initiated in 2020 by external stakeholders with EPA and other groups to be kind of exploring potential [TTC] applications under TSCA," Todd Stedeford, a branch chief in EPA's toxics office, said during an Oct. 20 presentation at the second annual conference the agency has hosted on new alternate testing methods (NAMs).

Stedeford described TTC as "basically a level of exposure that is considered to be no appreciable risk to human health despite the absence of chemical specific toxicity data." He also said that that EFSA and the World Health Organization have identified the TTC approach as "pragmatic, scientifically valid methodology to assess the safety of substances of unknown toxicity found in food."

In his presentation, Stedeford outlined how the concept might be used in assessing new chemicals or to prioritize existing chemicals for risk evaluation, both key concerns for EPA since Congress' extensive revisions to the law in 2016, which also encouraged the agency to step away from reliance on traditional animal toxicology methods in section 4(h).

Stedeford said use of the TTC approach "may justify waiving generation of animal data."

"I think is something we're going to delve into through that collaboration, to see is it really a fit for purpose NAM we could potentially use under [TSCA] new chemicals or existing chemicals [programs]," he said.

He acknowledged that while the TTC concept is "well established for oral exposure," its use in considering inhalation, dermal exposures and ecological risk is less developed, though he said approaches for these areas "have been proposed," including in recent publications by EPA scientists.

Answering questions after his presentation, Stedeford said collaborators will include external partners, experts in EPA's Office of Research and Development, and TSCA experts in the Office of Pollution Prevention and Toxics.

He said the participants already have a "potential draft list of topics we want to cover" and the agency will hold a kickoff meeting "sometime next month," adding that the project is "definitely in the early stages."

Asked for a list of the collaborators and the topics under consideration, an EPA spokesman tells Inside TSCA, "EPA intends to collaborate with scientists across the agency as well as members of the regulated community, NGOs, and academics. Topics that may be considered include potential applications of TTCs under section 5 and 6 of TSCA and dermal, inhalation, and ecological TTCs."

TSCA Prioritization

In his remarks, Stedeford noted that EPA flagged TTC in 2017 when it issued a draft strategic plan describing how officials would prioritize existing chemicals for risk evaluation. "The TTC approach is identified as a possible evaluation for its utility with priority setting," he said.

In September 2018, when the agency released the "Working Approach for Identifying Potential Candidate Chemicals for Prioritization" along with its response to public comments, Stedeford said, the agency stated that "exploration and implementation of the TTC approach, at least for some structural [chemical] classes is an important possible avenue for some TSCA decisions and EPA is considering this topic as part of collaborative effort."

EPA's 2018 working approach document describes how the agency will prioritize chemicals for possible assessment and regulation, though limited stakeholder consensus and TSCA's strict deadlines and minimum quotas of chemicals to

prioritize and assess existing chemicals led the agency to pursue a split approach for short- and long-term prioritization efforts.

The law requires EPA to have at least 20 high priority chemicals under evaluation at all times -- from December 2019 forward. For the short-term, including the 20 existing chemicals EPA prioritized for evaluation beginning earlier this year, the agency selected chemicals based on statutory language that requires at least half the substances be drawn from the Obama administration's list of work plan chemicals, which identified 90 substances for priority assessment.

So far, EPA has prioritized 30 chemicals from this list.

But the document also outlines a new, long-term approach that EPA is developing for use in the future, using a strategy to group or "bin" chemicals by toxicity and other attributes; this is where EPA is considering using TTC.

EPA "is considering a longer-term approach to bin the remaining chemicals (those not included on the 2014 TSCA Work Plan) on the TSCA active inventory. EPA currently expects to use an approach that integrates available information from both NAMs and traditional approaches, covering the domains of hazard, exposure, persistence, and bioaccumulation for human and ecological domains, to group chemicals based on information availability and hazard and exposure potential," the document says.

EPA describes the long-term approach in the new white paper as a "first step of developing this approach," adding that there will be another white paper and future public workshops, though these have yet to emerge.

"The bins will be defined using a combination of binning scores and information availability," EPA explains. "The binning scores included in the approach will incorporate human hazard relative to exposure, ecological hazard, genotoxicity, persistence, and bioaccumulation, further building upon prioritization approaches used in the TSCA 2012 Work Plan process and the objectives identified for integrating NAMs in the Canadian Chemicals Management Plan (CMP). Consistent with stakeholder feedback, this approach integrates NAMs to fill gaps when traditional testing data are not available."

The paper explains that "when both in vivo and in vitro studies are not available [for a particular chemical], a [TTC] would be calculated when appropriate and divided by the ExpoCast exposure estimate to provide a TTC-to-exposure ratio (TER)" to be considered as the "human hazard relative to exposure" criteria for binning scores.

EPA explains that its aim for the future binning approach will be to "attempt to identify a portion of the Active Inventory that can be set aside as not containing candidates for high-priority designation, so that EPA can focus on chemicals that are most likely to meet the statutory standard of high priority chemicals."

Stakeholder Comment

EPA's plan to use a TTC approach has drawn praise from industry groups. For example, the American Chemistry Council (ACC), in January 2018 comments, recommend that EPA "consider adopting [TTC] in its approach to identifying potential candidates for prioritization. TTC is a NAM used as a screening tool for safety assessment of chemicals when hazard data are incomplete and human exposure can be estimated."

"The TTC approach was derived from toxicity testing results from hundreds of chemicals and can be used to set safe levels of exposure for related chemicals (e.g. classes of chemicals) when they lack data," the group said.

The Humane Society of the U.S. also backed the approach, describing TTC as a "best practice," in its December 2017 comments.

Environmental groups, however, oppose use of the concept for prioritizing existing chemical evaluations, calling it "not a reliable tool for use in chemical prioritization." In its January 2018 comments, the Environmental Defense Fund (EDF)

said that using TTC for prioritization "would require extensive, reliable information on chemical structural characteristics and chemical exposures, including a robust understanding of how the chemical is metabolized."

EDF also charged that TTC "is based on the traditional assumption of toxicologists that there is a threshold of exposure below which there is no adverse effect. This assumption has increasingly been questioned by scientific experts, especially in the context of assessing effects on a diverse human population."

In particular, the group said, the approach is based on the "outdated concept that carcinogenicity is the most sensitive health endpoint when compared to non-cancer endpoints."

"The approach is rooted in decades-old toxicity data (which are used to develop the approach's pre-determined decision trees and thresholds) that were generated following testing protocols that do not reflect modern scientific principles and understandings of toxicity, nor real-world chemical exposures in a diverse human population," EDF said.

Specifically, EDF says TTC "does not adequately account" for issues including "[t]hresholds for health endpoints measured in adult animals do not represent or capture health effects observed in offspring after perinatal exposures"; "[s]ome chemicals exhibit non-monotonic dose-response curves that cannot be addressed using the TTC approach"; or "cumulative exposures from different chemicals or multiple routes of exposure to the same chemical." -- Maria Hegstad (mhegstad@iwpnews.com)

Environmental watchdog group alleges EPA allows company to violate environmental law
WWAY News
https://www.wwaytv3.com/2020/10/21/environmental-watchdog-group-alleges-epa-allows-company-to-violate-environmental-law/

HIGH POINT, N.C. (WWAY) — The toxic pollution watchdog, Center for Environmental Health, claimed today that companies have been importing thousands of pounds of a cancer-causing chemical from China without reporting it to the EPA, as is required by law.

The watchdog group says Hongda Group, headquartered in High Point, failed to inform the EPA about the import of more than 100,000 pounds of the hazardous chemical anthraquinone. Anthraquinone is toxic to aquatic animals and is a known carcinogen. Under the EPA's Toxic Substances Control Act (TSCA), these kinds of chemical imports must be reported to the agency every four years.

The group says, "Hongda hid the truth from regulators and endangered the health of North Carolinians."

Last year, Hongda lost a $27.8 million judgment resulting from complaints filed by a Chinese chemical manufacturer for failing to pay what it owed for importing another toxic chemical and also secretly importing it from other suppliers.

The EPA's newest chemical import report will be made public next month: November 2020.

EPA Draft Risk Assessment On Asbestos Flawed And Could Be Problematic For Automotive Friction Defendants
Saxon Guerriere, Mondaq
https://www.mondaq.com/Article/996882

The United States Environmental Protection Agency ("EPA") is currently conducting a chemical risk evaluation of asbestos. The EPA's 310-page Draft Risk Evaluation for Asbestos (the "Draft") identified risks for a variety of potential asbestos exposures. The Draft found that acceptable cancer risks were exceeded for much work with automotive brakes and clutches. If these findings are adopted in the final evaluation, defendants can expect asbestos plaintiffs' counsel to trumpet the evaluation to juries, even though (as described below and detailed in the attached article) the analysis is flawed and inconsistent with both the scientific literature and legal standards regarding cancer causation.

The Draft looked at exposures to occupational mechanics, bystanders, and do-it-yourself mechanics. The only asbestos fiber type the EPA evaluated was commercial chrysotile, and the only potential causative diseases the EPA evaluated were mesothelioma and lung cancer. The EPA chose to evaluate acceptable cancer risks to individuals based on an Inhalation Unit Risk of 0.16 per fiber/cc.

The Draft found that acceptable cancer risks were exceeded for brake and clutch installation and removal for occupational mechanics at both high-end and central tendency exposure levels and for occupational non-users at all high-end levels. For brake repair and replacement performed indoors with compressed air, the Draft found that acceptable risk levels were exceeded for do-it-yourself mechanics and bystanders of do-it-yourself mechanics at high-end and central tendency levels. For brake work performed outdoors, the Draft found that acceptable risks levels were exceeded for do-it-yourself mechanics at high-end tendency levels when mechanic work was performed 30 minutes per day with 62 years of cumulative exposure starting at age 16.

While the final risk assessment has not been published, the conclusions found in the current Draft lead to concern that these findings will cause confusion or even improperly influence jurors in future asbestos trials. A finding by the EPA that working with and around asbestos-containing brakes and clutches leads to an unacceptable risk of mesothelioma and lung cancer would be used in the opening statements of every asbestos plaintiffs' attorney in the country. Although the assessment is based on many assumptions that are not realistic, excludes large swaths of relevant scientific and medical studies, and makes conclusions regarding cancer causation that are entirely out of line with all current legal standards, it would be complicated and difficult to explain in necessary detail to a jury. It would simply be another factoid that will be used to persuade jurors that there is no safe level of chrysotile asbestos exposure and that all exposures cause disease. Surely, many hours of drafting and many tons of ink will be spilt in attempts to keep the findings of the EPA out of the courtroom through pre-trial motions to exclude and motions in limine. This is a future that will soon become all too real if there are not considerable changes made between the current Draft and the EPA's final risk evaluation.

Monsanto Review Bid Rejected in California Roundup Case

Joyce E. Cutler, Bloomberg Law

https://news.bloomberglaw.com/environment-and-energy/monsanto-review-bid-rejected-in-california-roundup-case?usertype=External&bwid=00000175-4bf4-d8a8-a377-7ff462200001&qid=6998573&cti=FGOV&uc=1320000080&et=NEWSLETTER&emc=neve_nl%3A9&source=newsletter&item=headline&region=digest&access-ticket=eyJjdHh0IjoiTkVWRSIsImlkIjoiMDAwMDAxNzUtNGJmNC1kOGE4LWEzNzctN2ZmNDYyMjAwMDAxIiwic2lnIjoieDFVMlFTc2I5eWg2a2VsMmpOaHhoQ0RYWXJRPSIsInRpbWUiOiIxNjAzMzY0NTU3IiwidXVpZCI6InBudE56OVQ2K09zbUdCY2xxeVBKZlE9PUt6Q2I6UXRhRjBTSE1NZVhzdlB0SEE9PSIsInYiOiIxIn0%3D

- World's most widely used pesticide blamed for cancer
- Case returns to trial court for damage award reduction

Bayer AG's Monsanto Co. lost a bid for the California Supreme Court to review the first multimillion-dollar jury award to someone alleging the widely used pesticide Roundup caused their cancer.

The justices on Wednesday declined to review an appellate decision rejecting the chemical giant's arguments that California school groundskeeper Dewayne Johnson failed to establish company liability for his non-Hodgkin's lymphoma.

A San Francisco jury in 2018 awarded Johnson $289 million, an award that was later reduced to $78.6 million. The appeals court validated Johnson's claim and reduced the award to $20.5 million. Johnson also asked the court to review the ruling, which now returns to the trial court.

"We are unpersuaded by Monsanto's argument that it could not be found liable under the consumer-expectations test because Johnson relied on the testimony of several experts," the San Francisco-based appeal court's July ruling said.

The company maintains that Roundup doesn't cause cancer. The International Agency for Research on Cancer in 2015 labeledglyphosate, the active ingredient in Roundup, a probable carcinogen.

Bayer has a few months to decide whether to appeal the ruling to the U.S. Supreme Court, said R. Brent Wisner, a senior partner with Baum Hedlund Aristei & Goldman PC in Los Angeles, representing Johnson.

"The fact that he's alive today and he's still with us, and I'm hoping he makes it to the end when they finally write the check, he'll know he finally beat them," Wisner said.

The company in a statement said it will "consider our legal options for further review of this case."

Three appeals are pending in the Roundup litigation, including one scheduled for oral argument Friday in the U.S. Court of Appeals for the Ninth Circuit involving issues central to the Johnson case.

The state appellate panel rejected the central argument Bayer is relying on to overturn verdicts in three California cases it's appealing. The company claims the U.S. Environmental Protection Agency has reviewed and approved the Roundup warning label and that the suits ignored the agency's authority.

Federal regulation of Roundup, Bayer argues, preempts California law.

None of the cases is covered by the company's $11 billion agreement announced in June to resolve massive litigation over Roundup. Bayer has resolved at least 47,000 of the suits.

The case is Johnson v. Monsanto Co., Cal., No. S264158, review rejected 10/21/20 \

Occidental Chemical Defeats Central Americans' Pesticide Suit

Martina Barash, Bloomberg Law

https://news.bloomberglaw.com/environment-and-energy/occidental-chemical-defeats-central-americans-pesticide-suit?usertype=External&bwid=00000175-4c41-d804-a97f-dee1a35f0001&qid=6998573&cti=FGOV&uc=1320000080&et=NEWSLETTER&emc=neve_nl%3A42&source=newsletter&item=headline&region=digest&access-ticket=eyJjdHh0IjoiTkVWRSIsImlkIjoiMDAwMDAxNzUtNGM0MS1kODA0LWE5N2YtZGVlMWEzNWYwMDAxIiwic2lnIjoicmlNSkhDU1ozRnpiSmV1QTJWSm1xZGRTLzgwPSIsInRpbWUiOiIxNjAzMzY0NTU3IiwidXVpZCI6InBudE56OVQ2K09zbUdCY2xxeVBKZlE9PUt6Q2I6UXRhRjBTSE1NZVhzdlB0SEE9PSIsInYiOiIxIn0%3D

- New York recognizes cross-jurisdictional class action tolling
- Conditional dismissal ended tolling in case

A 2012 suit by Costa Rican workers allegedly harmed by an Occidental Chemical Corp. pesticide is untimely because a tolling, or pause, of the statute of limitations came to an end before they filed suit, New York's high court ruled.

New York recognizes the tolling of the statute of limitations for absent class members of a putative class action filed in another jurisdiction under the principles of a 1974 U.S. Supreme Court case, American Pipe and Constr. Co. v Utah, the New York Court of Appeals held Tuesday.

But here, a conditional, non-merits dismissal of class certification in a proposed class action in Texas in 1995 terminated the tolling, the state top court said in a divided aspect of the ruling.

Tobias Bermudez Chavez and other plaintiffs alleged injuries from a nematicide called dibromochloropane (DBCP). Occidental allegedly distributed DBCP to banana plantations after it knew that the chemical could cause sterility, cancer, and other problems, according to the court. The plaintiffs argued their claims were timely because a class action filed in Texas state court in 1993 by plaintiffs from several countries tolled the statute of limitations. They were absent members of the proposed class, they said.

A long procedural path included a conditional dismissal in 1995, pending jurisdictional tests in the plaintiffs' home countries; a rejection of jurisdiction in Costa Rica; and a denial of class certification in Texas state court in 2010.

In 2011 and 2012, some absent class members filed suit in federal courts in Louisiana and Delaware. The Louisiana case was dismissed and the Delaware case was transferred to the U.S. District Court for the Southern District of New York, where Occidental is headquartered.

Occidental sought dismissal on statute of limitations grounds, which the district court denied. The U.S. Court of Appeals for the Second Circuit certified two questions to New York's high court: whether the state recognizes cross-jurisdictional class action tolling, and whether a non-merits dismissal can terminate that tolling.

Yes, the court said to both questions in an opinion by Judge Leslie E. Stein. Rejecting cross-jurisdictional tolling "would undermine the detailed class action statutory scheme crafted by the legislature," she said.

As to the second question, the "parties are in agreement that tolling terminates when it is no longer objectively reasonable for absent class members to rely upon the putative class action to vindicate their rights," she said. A non-merits dismissal of class certification—in this case, the 1995 Texas state court's orders—can end class-action tolling, she said.

Judge Jenny Rivera, joined by two other members of the court, dissented in part. "Tolling should end only upon a dismissal that is unconditional, meaning that the court leaves potential plaintiffs without any expectation of an opportunity for future class certification," she said.

Massey & Gail LLP and the Hendler Flores Law Firm represented the plaintiffs. Young Conaway Stargatt & Taylor LLP, Arnold & Porter Kaye Scholer LLP, Gibbs & Bruns LLP, and Vinson & Elkins LLP represented Occidental Chemical.

The case is Bermudez Chavez v Occidental Chem. Corp., 2020 BL 403330, N.Y., No. 39, 10/20/20.

BAYER LAUNCHES ROUNDUP POWERMAX 3 HERBICIDE

Successful Farming
https://www.agriculture.com/crops/pesticides/bayer-launches-roundup-powermax-3-herbicide

Bayer is launching Roundup PowerMAX 3 herbicide – a new formulation within the Roundup brand of agricultural herbicides. The latest formulation contains a new proprietary surfactant blend with high-performing weed control, say Bayer officials. Over a three-year launch, this new crop protection product will be introduced initially in the Southeastern states in year one, with plans of expansion throughout the United States in years two and three.

Compared to generic herbicide products on the market, as well as the 45-year history of current Roundup brand agricultural herbicides, the new formulation has the highest concentration of glyphosate on the U.S. market, say Bayer officials. This highly concentrated product enables growers to spray more acres with less product, which allows for less packaging and bulk trucks on the road, say Bayer officials.

NEW SURFACTANT BLEND

Roundup PowerMAX 3 introduces a new proprietary surfactant blend. This exclusive surfactant enables fast absorption and provides growers with more consistent control over weeds by allowing translocation throughout the plant, including the root system.

"Roundup PowerMAX 3 brings a new level of innovation into the long history and success of Roundup brand agricultural herbicides," said Matt Muckerman, North American glyphosate portfolio lead, in a Bayer press release. "Bayer is excited to bring a high-quality, reliable performance through our branded glyphosate crop protection products."

Bayer's proprietary CROPSHIELD technology provides high levels of crop safety on glyphosate tolerant crops, say Bayer officials.

Roundup PowerMAX 3 has already sold over 500,000 gallons in its initial launch, with the first delivery of the new formulation completed at Nutrien AG Solutions in Guntown, Mississippi, say Bayer officials.

Roundup brand agricultural herbicides are the only glyphosate products included in Bayer PLUS Rewards – a broad portfolio of products designed to provide growers with flexibility and rewards on eligible purchases all season long, say Bayer officials.

WSSA Announces Opposition to Weakening of FIFRA Regulations

Cision PRWeb

https://www.prweb.com/releases/wssa_announces_opposition_to_weakening_of_fifra_regulations/prweb17487082.htm

The Weed Science Society of America (WSSA) and its national and regional affiliates have joined with more than 300 agriculture and conservation organizations to protest legislation that would change our science-based pesticide laws.

Currently pesticides are regulated by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The law specifies that career scientists in the U.S. Environmental Protection Agency (EPA) are responsible for determining whether a given pesticide is safe, whether it should be registered and how it should be used. Proposed bills introduced in the House (H.R. 7940) and the Senate (S. 4406) would put science in the backseat and let politics drive such decisions, WSSA says.

For example, the legislation would allow any interested person to submit a petition to designate an active ingredient or pesticide product as dangerous – regardless of the individual's background, motives or scientific data supporting its safe use.

In addition, any pesticide banned for use in the European Union or Canada for any reason would be immediately banned within the United States, even if extensive EPA scientific reviews have determined it is safe to use. The EPA's risk-benefit assessments are widely recognized as the "gold standard." In fact, many countries align with or defer to the EPA's regulatory decisions because of their scientific rigor. Yet the legislation would allow these science-based decisions to be overthrown by less comprehensive analyses.

WSSA says decades of federal regulation and scientific progress will be gutted if the legislation passes.

"These bills would significantly undermine the work of the EPA," says Lee Van Wychen, executive director of science policy for WSSA. "They would impose an unscientific and unbalanced process that would jeopardize the continued availability of herbicides and would deter companies from investing in new innovations. Ultimately, the United States could lose the pest control options we need to grow crops safely, protect our homes and infrastructure, control pathogens and diseases, and maintain parks, golf courses and natural areas."

A letter to members of the Senate and House of Representatives opposing this legislation (http://wssa.net/wp-content/uploads/Neguse-Udall-FIFRA-letter.pdf) was endorsed by WSSA, the Aquatic Plant Management Society, the North Central Weed Science Society, the Northeastern Weed Science Society, the Southern Weed Science Society and the Western Society of Weed Science.

About the Weed Science Society of America

The Weed Science Society of America, a nonprofit scientific society, was founded in 1956 to encourage and promote the development of knowledge concerning weeds and their impact on the environment. The Society promotes research, education and extension outreach activities related to weeds, provides science-based information to the public and policy makers, fosters awareness of weeds and their impact on managed and natural ecosystems, and promotes cooperation among weed science organizations across the nation and around the world. For more information, visit http://www.wssa.net.

EPA's Draft Residual Efficacy Protocols for "Long-Lasting" Efficacy for Antiviral Products

Lisa M. Campbell, Heather F. Collins, M.S & Barbara A. Christianson, B&C Pesticide Law and Policy Blog

http://pesticideblog.lawbc.com/entry/epas-draft-residual-efficacy-protocols-for-long-lasting-efficacy-for-antivi

On October 14, 2020, the U.S. Environmental Protection Agency (EPA) released a much-anticipated draft guidance that will allow companies to demonstrate that their products have "long-lasting" or "residual" effectiveness on surfaces against viruses like SARS-CoV-2, the coronavirus that causes COVID-19. EPA's guidance specifies scientific testing requirements for two different types of products: (1) disinfectants that also provide residual efficacy, and (2) supplemental residual antimicrobial products (e.g., coatings, paints, solid surfaces) that do not meet EPA's standards for disinfectants but are intended to be used as a supplement to standard List N disinfectants.

In addition to releasing the draft residual efficacy protocols, EPA has also released an updated draft testing protocol for evaluating a copper surface's ability to kill bacteria and a draft protocol for evaluating the efficacy of antimicrobial surface coatings. These laboratory testing methods act as a foundation for EPA's interim guidance to registrants regarding residual effectiveness.

While EPA does not have an approved standard method to support virus claims for these types of products, EPA states that the following information is intended to provide interim guidance on the study design elements necessary to support these types of claims. EPA states that it may consider other methods or studies to support residual efficacy claims, provided they are scientifically sound. Applicants are highly encouraged to consult with EPA prior to submitting. Of significant interest, EPA states that products may make both types of residual claims provided that they are supported by the appropriate data.

Due to lab capacity concerns, EPA plans to consider non-GLP (Good Laboratory Practice) data to support residual claims, provided that the study submission accurately represents how the study differs from the GLP standards in the 40 C.F.R. Section 160.12 statement of non-compliance. Additional details provided in the EPA guidance on how to qualify products for residual disinfectants or supplemental residual antimicrobial products are briefly outlined below.

Residual Disinfectant Claims

Residual disinfectants must clear a higher standard of efficacy than supplemental residual antimicrobial products. Residual disinfectant products must be effective within 10 minutes of a virus or bacteria contacting a treated surface and must remain effective for up to 24 hours. Surfaces treated with residual disinfectants must not require additional cleaning or disinfection during this window. EPA-approved residual disinfectant products are eligible to be added to List N. In addition, long-lasting coating products must satisfy all requirements for standard disinfectant claims (non-residual) to be eligible for residual disinfectant claims and must have undergone testing to support standard disinfectant claims.

To support a claim as a residual bactericidal disinfectant, applicants should use EPA's Residual Self-Sanitization Protocol with the following modifications:

- Base Bacteria -- Consistent with EPA Guideline 810.2200, Staphylococcus aureus (ATCC No. 6538) and Pseudomonas aeruginosa (ATCC No. 15442) should be used to support the case residual disinfectant claim.
- Conduct testing on three product lots at the lower certified limit (LCL) for each bacterium. In accordance with the OCSPP 810.2000 Test Guideline, certificates of analysis should be submitted to substantiate the tested concentration.
- Residual testing to support additional vegetative bacteria is not needed. Claims can be bridged from the standard disinfectant (non-residual data) for additional bacteria. For example, if a product has data to support a base disinfectant claim (Staphylococcus aureus and Pseudomonas aeruginosa) and data to support disinfectant claims for additional vegetative bacteria (e.g., Escherichia coli or MRSA), residual data are only needed for the base bacteria, and not additional bacteria, to support residual claims for those vegetative bacteria for which base disinfectant claims are supported.
- According to the Residual Self-Sanitization Method, durability testing should include 12 wear cycles, consisting of abrasions (alternating wet and dry) and re-inoculations to support a 24-hour residual disinfectant claim. Each wear cycle consists of four passes (two back and forth) of the abrasion material over the surface followed by re-inoculation. Additional details can be found in the method.

- Products should achieve a ≥ 5-log reduction in ≤ 10 minutes ± 5 seconds for qualifying bacteria when compared to the parallel abrasion and re-inoculation controls to support residual disinfectant claims.
- According to the OCSPP 810.2200 Test Guideline, the performance standard and time to meet the performance standard are consistent with the standards for non-residual disinfectants.
- At this time, expedited review is limited to residual disinfection claims of 24 hours or less based on data generated in accordance with the re-inoculation and abrasion cycles specified in the referenced protocol.

A. Residual Virucidal Claims

EPA's Residual Self-Sanitization Protocol with the modifications below should be used to support residual virucidal claims. Virucidal efficacy should be assessed consistent with the principles of ASTM E1053 (e.g., recovery, cytotoxicity, neutralization, and calculations), the standard virucidal method detailed in OCSPP 810.2200 Product Performance Test Guideline.

- To support residual virucidal claims, acceptable non-residual virucidal efficacy (3-log reduction) should be demonstrated for the product at ≤ 10-minute contact time consistent with the OCSPP 810.2200 Product Performance Test Guideline.
- Residual virucidal data should be generated for the most difficult to kill virus that that the product claims to kill. Claims for residual effect against the other viruses can be bridged from the non-residual virucidal data supporting the product. For additional information on selecting the most difficult to kill virus, see EPA's Emerging Viral Pathogens Guidance.
    - To be considered for List N, virus testing should include a non-enveloped virus or a human coronavirus (SARS-CoV-2 or human coronavirus 229E).
- Testing on two product lots should be conducted at the LCL.
- According to the Residual Self-Sanitization Method, durability testing should include 12 wear cycles consisting of abrasions (alternating wet and dry) and re-inoculations to support a 24-hour residual disinfectant claim. Each wear cycle consists of four passes of the abrasion material over the surface followed by re-inoculation. Additional details can be found in the method.
- Products should achieve ≥ 3-log reduction in ≤ 10 minutes ± 5 seconds for the hardest to kill virus when compared to the parallel abrasion and re-inoculation controls to support residual virucidal claims.
    - The performance standard and contact times are consistent with the standard non-residual disinfectants.
- At this time, expedited review is limited to residual disinfection claims of 24 hours or less based on data generated in accordance with the re-inoculation and abrasion cycles specified in the referenced protocol.

B. Labeling and additional information (both bactericidal and virucidal)

- Products are eligible for inclusion on List N following adherence to the Emerging Viral Pathogens guidance or appropriate testing for a qualifying virus (e.g., SARS-CoV-2 or human coronavirus 229E).
- These products may be used as stand-alone disinfectants and do not need a label disclaimer that they are a "supplement to standard disinfection" since they meet the general criteria for disinfectants (effective in ≤ 10 minutes with appropriate log reductions for bacteria and virus).

Supplemental Residual Antimicrobial Products

Supplemental residual antimicrobial products work within two hours of a virus or bacteria coming into contact with a surface and can remain effective for weeks to years. These products can supplement, but not replace, routine cleaning and disinfection using products from EPA's List N: Disinfectants for Use Against SARS-CoV-2 (COVID-19). Approved supplemental residual antimicrobial products are not eligible for inclusion on List N, but will be added to a separate List N appendix.

Qualifying antimicrobial surface coatings, films, fixed/solid, and paint products should demonstrate efficacy against vegetative bacteria first before virus claims can be supported. These products are not required to meet the efficacy standards for disinfectants and can only be approved for use as supplements to standard disinfection. The duration of

residual effectiveness claims that EPA will consider for expedited review depends on the type of product, as outlined below.

Antimicrobial Surface Coatings and Films
For these products, EPA states that EPA's draft Performance of Antimicrobial Surface Coatings on Hard Non-porous Surfaces for qualifying bacteria should be used. EPA provides the following additional information for products on which virus claims would be added:

- Test Organisms
- Bacteria -- Staphylococcus aureus (ATCC No. 6538) and Pseudomonas aeruginosa (ATCC No. 15442) are the qualifying bacteria required to support supplemental residual antimicrobial surface claims for the proposed claim duration (e.g., one week, two weeks).
    - Testing should be conducted on three product lots per bacterium at the LCL.
- To support claims for additional bacteria, testing should be conducted according to the method but with a reduced number of product lots.
    - Two lots of product for each bacterium at the nominal concentration.
- Viruses -- All viruses for which claims are desired should be tested. The most difficult to kill virus should be subjected to the durability assessment using coating carriers followed by the efficacy assessment to support the proposed duration (e.g., one week, two weeks). All other viruses should be tested using coated carriers that were not subjected to the durability procedure.
    - Assessment of virucidal efficacy on the coated carriers should be conducted consistent with ASTM E1053, the standard method specified in EPA's 810.2200 Efficacy Test Guideline.
    - Two lots of product at the LCL should be tested for the most difficult to kill virus. Two lots of product at the nominal concentration should be tested for additional viruses.
        - To be considered as a supplement to List N, virus testing should include a non-enveloped virus or a human coronavirus (SARS-CoV-2 or human coronavirus 229E).
- Stainless steel carriers will be used to support claims for coatings on hard, nonporous surfaces. Use sites should be limited to hard, non-porous surfaces. Additional material types (e.g., porous materials or textiles) may be proposed by the registrant upon consultation with EPA prior to submission.
- The recommended number of abrasions (touches) and cycles of exposure to cleaning or disinfecting chemicals are provided in the method to substantiate durability claims. The method also specifies the chemical disinfecting solutions to simulate cycles of in-service disinfection and cleaning. Additional details can be found in the method.
    - Ten cycles of abrasion and/or chemical exposure is equivalent to one week of durability. The number of cycles can be increased in one-week increments to support claims up to four weeks.
    - If a product is incompatible with one or more of the test chemistries, this should be discussed with EPA in advance and may limit use sites and surfaces depending on the nature of the incompatibility. EPA does not have a standard method for determining incompatibility. This may be based on research and development data or known incompatibilities with the coating material, for example.
- This protocol may be modified for films upon consultation with EPA in advance of submission.
- If an applicant intends to claim supplemental residual effects longer than four weeks, it should consult with EPA in advance of submission. EPA states that because the ongoing antimicrobial integrity of coatings and films will not be readily visible, it is important that end users have a reasonable expectation of durability.
- Products should achieve a 99.9% reduction (3-log) for both bacteria and viruses in comparison to untreated controls within a maximum of two hours but not less than one hour, as EPA is concerned that observations taken before the inoculum has dried (e.g., less than one hour) on the surface may not provide an accurate assessment of the product.
    - The time to achieve performance begins at the time of inoculation.

B. Antimicrobial Surface Coatings and Films -- Labeling and Additional Information

EPA states that this new category of antimicrobial products should be labeled as supplemental residual antimicrobial surfaces. EPA provides the following additional information:

- As these products do not meet the criteria for a disinfectant due to the longer contact time and lower performance standard, claims for residual disinfectant are not acceptable. As above, contact times for disinfectants are ≤ 10 minutes and with a higher performance standard for bacteria.
- Products should carry the following prominent label qualifier that they are a supplement to standard disinfection and cleaning:
    - "Although this product DOES NOT meet EPA's standards for disinfectants, EPA has determined that, when used with an EPA-registered disinfectant, this product can provide some additional protection against [microorganism(s)] for up to X days. This product DOES NOT achieve the same level of efficacy as an EPA-registered disinfectant; it is only intended to provide supplemental protection between routine applications of EPA-registered disinfectants."
- For products eligible only for supplemental residual antimicrobial claims, EPA intends to require as a term of registration that the label and labeling state, "This product does not meet EPA's efficacy standards to qualify as a stand-alone disinfectant."
- Although these products will not be eligible for List N, they will be eligible as a supplement to List N (N.1) to reflect that they are supplemental treatments (i.e., not stand-alone disinfectants) and intended for use in combination with List N disinfectants.
- The following are example acceptable product label claims:
    - "Kills 99.9% of [insert microorganism/s] within two hours of exposure when used as part of a comprehensive infection control program/protocol for up to X days."
    - "Continuously reduces [insert microorganism/s] within two hours of exposure when used as part of a comprehensive infection control program for up to X days."

C. Fixed/Solid Surfaces Including Solid Copper and Other Metals and Solid Impregnated Materials and Paints -- Method Recommendation

EPA states that these products should use EPA's Draft Copper Surface Protocol for qualifying bacteria. EPA provides the following additional information for products that wish to have virus claims added.

- Test Organisms
    - Bacteria -- Staphylococcus aureus (ATCC No. 6538) and Pseudomonas aeruginosa (ATCC No. 15442) are the qualifying bacteria used to support supplemental residual surface claims.
        - Testing should be conducted on three product lots per bacterium at the LCL.
    - To support claims for additional bacteria, testing should be conducted according to the method but with a reduced number of product lots.
        - Two lots of product for each bacterium at the nominal concentration.
    - Viruses -- All viruses for which claims are desired should be tested. The most difficult to kill virus should be subjected to the durability assessment in the copper method, followed by the efficacy assessment. All other viruses should be tested using test carriers that were not subjected to the durability procedure.
        - Assessment of virucidal efficacy on the coated carriers should be conducted consistent with ASTM E1053, the standard method specified in EPA's 810.2200 Efficacy Test Guideline.
        - Two lots of product at the LCL should be tested for the most difficult to kill virus. Two lots of product at the nominal concentration should be tested for additional viruses.
- The recommended number of abrasions (touches) and cycles of exposure to cleaning or disinfecting chemicals are provided in the method in order to substantiate durability claims. The method also specifies the chemical solutions to simulate cycles of disinfection and cleaning.
    - As the durability of these types of products can be readily observed, duration claims are not necessary. This is consistent with currently registered copper-containing surface products and paints.

- If a product is incompatible with one or more of the test chemistries, this should be discussed with EPA in advance and may limit use sites and surfaces, depending on the nature of the incompatibility. EPA states that it does not have a standard method for determining incompatibility. This may be based on research and development data or known incompatibilities with the coating material, for example.
- This protocol can be modified for other metals or solid impregnated surfaces or paints upon consultation with EPA.
- Products should achieve a 99.9% reduction (3-log) for both bacteria and viruses in comparison to untreated controls within two hours.
- The time to achieve performance begins at the time of inoculation.

D. Fixed/Solid Surfaces Including Solid Copper and Other Metals and Solid Impregnated Materials and Paints -- Labeling and Additional Information

EPA states that these products should be labeled as supplemental residual antimicrobial surfaces. EPA states the following with regard to these products:

- As these products do not meet the criteria for a disinfectant due to the longer contact time and lower performance standard, claims for residual disinfectant are not acceptable.
- Products should carry the following prominent label qualifier that they are a supplement to standard disinfection and cleaning:
    - "Although this product DOES NOT meet EPA's standards for disinfectants, EPA has determined that, when used with an EPA-registered disinfectant, this product can provide some additional protection against [microorganism(s)] for up to X days. This product DOES NOT achieve the same level of efficacy as an EPA-registered disinfectant; it is only intended to provide supplemental protection between routine applications of EPA-registered disinfectants."
- For products eligible only for supplemental residual antimicrobial claims, EPA intends to require as a term of registration that the label and labeling should state, "This product does not meet EPA's efficacy standards to qualify as a stand-alone disinfectant."
- Although these products will not be eligible for List N, they will be eligible as a supplement to List N (N.1) to reflect that they are supplemental treatments (i.e., not stand-alone disinfectants) and intended for use in combination with List N disinfectants. The following are example acceptable product label claims:
    - "Kills 99.9% of [insert microorganism/s] within two hours of exposure when used as part of a comprehensive infection control program/protocol."
    - "Continuously reduces [insert microorganism/s] within two hours of exposure when used as part of a comprehensive infection control program."

E. Supplemental Residual Antimicrobial Products -- Stewardship Program

EPA intends to require, as a term of registration, that registrants of all supplemental residual antimicrobial products prepare and implement a written stewardship plan designed to support the responsible use of supplemental residual coatings and antimicrobial surface products. Unlike conventional antimicrobial products, EPA believes that these products represent unique challenges that require timely feedback to ensure proper use and compatibility in combination with current infection control practices. EPA expects that plans would be submitted for EPA review and approval during the registration process, or shortly thereafter (e.g., within two months after the registration date). An approvable plan would address the proper sale (including advertising and promotional materials), distribution, and responsible use of the supplemental residual coatings and antimicrobial surface products. EPA states that plans should include, at a minimum, the following elements:

- Advertising and promotional materials that clearly and consistently include a disclaimer that the product does not meet EPA's standards for disinfectants and is intended to supplement the use of EPA-registered disinfectants.
- Outreach to the infection control community;

- Customer feedback consisting of product issues/concerns, adverse events, compliance challenges/observations, and contraindications/adverse events gathered through quarterly registrant-initiated surveys, customer complaints, and suggestion boards; and
- Development of a stewardship website.

EPA states further that "if EPA determines at any time following registration that the Plan is not being adequately or timely implemented or does not effectively ensure the product's safe and effective use, the registration may be cancelled by the Agency." It is not clear from the statement whether EPA intends such a cancellation to be a term of the registration or whether it would be undertaken pursuant to the standard FIFRA cancellation procedures.

EPA Reminds Companies of November 1 Deadline to Submit CBI Substantiations for NOA Form A

Lynn L. Bergeson & Carla N. Hutton, The National Law Review (Bergeson & Campbell)
https://www.natlawreview.com/article/epa-reminds-companies-november-1-deadline-to-submit-cbi-substantiations-noa-form

On October 16, 2020, the U.S. Environmental Protection Agency (EPA) reminded companies that if they filed a retrospective activity notice (Notice of Activity (NOA) Form A) under the Toxic Substances Control Act (TSCA) Inventory Notification (Active-Inactive) Rule and claimed the specific chemical identity as confidential business information (CBI), they have until November 1, 2020, to submit or amend their CBI substantiations. Companies that amend, update, or file new CBI substantiations must do so electronically via EPA's Central Data Exchange.

Background
On March 6, 2020, EPA promulgated a final rule on procedures for review of CBI claims made under TSCA. The final rule includes the requirements for regulated entities to substantiate certain CBI claims made under TSCA to protect the specific chemical identities of chemical substances on the confidential portion of the TSCA Inventory, and EPA's plan for reviewing certain CBI claims for specific chemical identities. The substantiation requirements describe the applicable procedures and provide instructions for regulated entities. EPA sets out the review criteria and related procedures that it will use to complete the reviews within the five-year timeframe set in TSCA. More information is available in our February 28, 2020, memorandum, "EPA Releases Final Rule on Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory."

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